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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/629,557	07/31/2000	Dwight W. Miller	4239-55412	4093

7590 02/03/2003

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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 02/03/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/629,557

Applicant(s)

MILLER ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26,55-58 and 65-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26,55-58 and 65-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8, 9 6) ☐ Other: _____

DETAILED ACTION

Claims 66-90 have been newly introduced. Claims 1-26, 55-58, and 65-90 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 1-17, 25, 55, 65-90 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to recite a scaling step. Applicant points to page 19, lines 11-13 for basis. However, this portion of the specification indicates that the spectral data is segmented into bins and scaled prior to pattern recognition. The claims as amended do not reflect these other aspects and the specification does not disclose scaling in their absence.

Claim 69 recites providing biological activity data for a plurality of compounds as the first steps of the method. The claim also recites a single step of segmenting both the test compound and training compounds spectral data. Basis is stated to be on pages 9-10 and 13. However, this portion of the specification does not disclose providing biological data in and of itself. The training compounds have a known and specific biological activity. The training compounds have the same known activity. Generic biological activity data is not provided. Secondly, the training spectra are analyzed then the test compound spectra by detecting corresponding patterns. See also claim 82 which claims inputting biological activities.

Claim 65 has been amended to recite a method where a first biological property is predicted followed by prediction of a second biological activity. Basis is stated to be on pages 29 and 59. Page 29 discloses a discriminant function for a training set split into two endpoints. Page 59 is a generic discussion regarding screening compounds. The specification does not disclose nor contemplate method steps as set forth in this claim.

Claims 1-16, 18-26, 55-58, and 65-90 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for computer implemented methods and for deriving the pattern of spectral data associated with the biological activity from the spectral data of the training set of compounds by statistical and artificial intelligence, does not reasonably provide enablement for methods not using a computer nor for any other type of derivation,. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This is a scope of enablement rejection.

Applicant was advised in the prior Office action that the claimed methods were not described nor enabled for performing them in a non-computer environment nor without pattern recognition techniques. (See prior rejections under 112, 2nd paragraph, regarding clarity of the claims.) Applicant's response disputes this and points to page 28, lines 7-28. To the degree applicant's claims are directed to non-computer implementations, these implementations are not enabled. The disclosure on page 28, lines 7-28, does not perform the claimed methods in the absence of computer implementation and pattern recognition. Note that Figure 6 was generated by the SDAR model (see page 14 and page 28). Note that page 28 discusses pattern recognition

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techniques and software packages. None of claims 1-16, 25, 55, and 65-81 explicitly recites that the method is computer implemented. Claim 17 has been omitted from this ground of rejection as it recites “artificial intelligence pattern recognition” which implies a computer implementation. Claim 25 has been included in that although the claim is directed to a computer readable medium with instructions this is not explicitly directed to computer executable instructions (i.e. program code) and could mean a text file with written instructions.

The specification discusses pattern-recognition programs useful for practicing the invention as being of two major types: statistical and artificial intelligence. No other pattern-recognition programs are disclosed. No guidance on using any other methods for deriving the pattern of spectral data associated with the biological activity from the spectral data of the training set of compounds are disclosed. No guidance on using any other methods for detecting a pattern of spectral data associated with the biological activity and comparing it to the spectral data of the test compound are disclosed. Claim 1 uses “deriving” language. Claims 18, 69, and 82 use “detecting” language. Note that claim 19 specifies that the statistical pattern recognition program is with respect to the comparing step but not the detecting step.

Claims 1-26, 55-58, and 65-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires predicting the biological activity of the test compound by “detecting similarities.” The claim fails to make clear how similar the patterns of spectral data must be in order to assign or predict that it will have the activity of the training set of compounds. It cannot

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be determined what level of similarity would meet the limitation of the claims. See also claims 69 and 82.

Claim 5 recites “substantially the same.” It cannot be determined what level of segmenting would meet the limitation of the claims. See also at least claims 10 and 20.

Claim 17 is confusing in reciting “wherein the method comprises artificial intelligence pattern recognition.” The method of claim 1 includes steps concerning data preparation (obtaining, scaling etc.). It appears that applicant may have been intending to further specify the method by which deriving the pattern of spectral data associated with the biological activity is achieved. However, this is not clear.

Claim 18 recites “spectral data of the test compound is similar.” Again, it cannot be determined what level of similarity would meet the limitation of the claims.

Claim Rejections - 35 USC § 102

Claims 1-10, 14-15, 18-21, 25-26, 55-58, 66-68 are rejected under 35 U.S.C. 102(a) as being anticipated by Bursi et al.

Bursi et al. discloses predicting biological activity for test compounds from their IR, mass, ¹H NMR, and ¹³C NMR spectra as descriptors in 3D modeling. A training set of 38 progesterone compounds of known binding activity was used. Some were experimental and some were simulated (calculated). (See page 864, left column, under Results.) Different combinations of spectra were analyzed for their predictive ability. The spectra properties (peaks and intensities) are binned. (See page 862 under Computational Details.) Data conversion was performed on the spectral data to present the data in an appropriate format for analysis. (See page 862.) This is deemed to meet the limitation of scaling.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

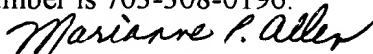
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
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npa
January 30, 2003